DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 20, 2010 has been entered.

Claims 8 and 12-32 are pending. Claims 1-7 and 9-11 are cancelled, and claims 12-32 are new.

Election/Restrictions

Applicant's election of Group I, claim 8, and imiquimod as the compound in the reply filed on June 13, 2011 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claim 8 is examined on the merits with the species election imiquimod as the IRM compound. Claims 12-32 are withdrawn as belonging to non-elected groups.

For the reasons in the previous office action and below, the Applicant's arguments of the following rejections were found not persuasive, thus the rejections are upheld: 1) the 35 USC 112, first paragraph rejection of claim 8; and the 2) 35 USC 103(a) rejection of claims 8 as being unpatentable over Yu et al. in view of Maibach et al.

Due to the no new amendments to the claims and the Applicant's arguments not being persuasive, the previous rejections are repeated below. The Applicant's arguments are addressed below.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 8 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no written description on how to administer all of the different types of classes of IRM compounds (even those that are TLR7 agonist) other than imiquimod. For instance, the differences in structural features of the different classes of compounds disclosed in claim 8 will result in different reactivity, solubility, bioavailability, etc. Thus, by virtue of the different structures and reactivity of these compounds, the efficacy will inherently be different. One would need to perform further experimentation to acquire the effectiveness and the amounts of each IRM compound in prior art in order to practice the invention. Genetech, 108 F. 3d at 1366 states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimation of general ideas that may or may not be workable.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yu et al. (US 6,335,023 B1) in view of Maibach et al. (US 2003/0072724 A1).

Yu et al. teaches a method of treating cosmetic conditions or dermatoligical disorders comprising topically applying a topically acceptable vehicle, at least one compound selected from the group consisting of oligosaccharide aldonic acids, and a cosmetic, pharmaceutical or topical agent such as imiquimod (see claims 10, 31 and 42). Cosmetic conditions or dermatological disorders include changes associated with aging skin such as age spots, hyperpigmented skin and wrinkles (see claim 40). The compositions may be formulated as a solution, gel, lotion, cream, ointment, spray, or

other forms acceptable for use on skin (see column 17, lines 49-52). Yu et al. teaches that with increasing age and exposure of human to sun and other environmental traumas, cells divide at a slower rate showing marked irregularities in size, shape; orderliness; epidermis decrease (atrophy). The cells make the fibers of the dermis become smaller and sparser with increasing age. There is a great loss of collagen fibers resulting in looseness and easy stretchability of the skin; elastic fibers become abnormal so that the skin does not promptly snap back after being stretched. Degradation of these fibers, especially collagen is mainly responsible for wrinkling, laxness and loss of elasticity (see column 9, lines 11-17 and 33-42).

Yu et al. does not specifically teach applying imiquimod to treat of wrinkles.

Maibach et al. teaches a treatment of an individual predisposed to or afflicted with skin hyperpigmentation, and comprises topically administering to the individual's affected skin area a pharmaceutical formulation containing a therapeutically effective amount of an agent active for treating skin hyperpigmentation (see page 4, paragraph 44, lines 1-7). A preferred embodiment is the treatment of age spots, which is age-related and hence is common among the elderly (see page 5, paragraph 45, lines 5-8). Active agents include any compound that effectively treats warts such as imiquimod (see page 8, paragraph 92, lines 1-3 and 7). Treatment is to improve or remediate damage, which is exemplified in examples 4 and 5 by the lightened skin regaining essentially normal skin color after eight weeks of treatment (i.e. visibly reducing a skin

change associated with aging and improving the quality of the skin; addresses claims 1, 7, 9 and 10).

To one of ordinary skill in the art at the time of the invention would have found it obvious and motivated to combine the method of Yu et al. and applying imiquimod to treat of wrinkles because of the following teachings: (1) Yu et al. teaches a method of treating cosmetic conditions or dermatoligical disorders changes associated with aging skin such as age spots, hyperpigmented skin and wrinkles (see claim 40), with a cosmetic, pharmaceutical or topical agent such as imiquimod (see claims 10, 31 and 42); (2) Maibach et al. teaches a treatment for the age related skin condition age-spots or hyperpigmented skin, in which the active ingredient is imiquimod (see page 5, paragraph 45, lines 5-8 and see page 8, paragraph 92, lines 1-3 and 7); and (3) Yu et al. teaches that with increasing age and exposure of human to sun and other environmental traumas, cells divide at a slower rate showing marked irregularities in size, shape; orderliness; epidermis decrease (atrophy). The cells make the fibers of the dermis become smaller and sparser with increasing age. There is a great loss of collagen fibers resulting in looseness and easy stretchability of the skin; elastic fibers become abnormal so that the skin does not promptly snap back after being stretched. Degradation of these fibers, especially collagen is mainly responsible for wrinkling, laxness and loss of elasticity (see column 9, lines 11-17 and 33-42). Thus, one would be motivated to try the treatment of age related skin conditions such as wrinkles with the active ingredient imiquimod, because it also treats the age-related skin condition of age-

spots or hyperpigmented skin, which also results in the fibers of the dermis becoming smaller and sparser with increasing age.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KENDRA D. CARTER whose telephone number is (571)272-9034. The examiner can normally be reached on 9:00 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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